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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,496

Applicant(s)

DELOBEL ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 18-20 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15, 18-20 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed January 24, 2005 has been entered.

Claims 1-12, 14, 16-17 and 21-26 are cancelled.

Claims 13 and 15 are currently amended.

Claims 27-31 are newly added.

Claims 13, 15, 18-20 and 27-31 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claim 31 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 31 is directed to the use of a polypeptide for protecting cereal seeds or products from cereal seeds against pests, whereas both the originally presented and elected claims were drawn to the use of a protein to protect a plant from insects. Methods of using proteins to protect a plant are different from methods of using proteins to protect products derived from plants, and each method must be separately searched.

Applicant has received an action on the merits for the originally elected invention. Accordingly, claim 31 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The disclosure is objected to for the reasons of record set forth in the office action mailed September 22, 2004.

Applicant's arguments filed January 24, 2005 have been fully considered but they are not persuasive.

Applicants point out that the specification is amended to include a brief description of the drawings and Sequence Identifiers (SEQ ID NO:) where appropriate. (reply page 6)

The objection is maintained because while the submitted amendment does include a brief description of the drawings, the submitted amendment does not include Sequence Identifiers (SEQ ID NO:) where appropriate. Appropriate correction or clarification is required.

Claim Objections

Claim 13 is objected to for the reasons of record set forth in the office action mailed September 22, 2004.

Applicant's arguments filed January 24, 2005 do not address this objection.

Claim 13 is objected to because the claim does not comply with the sequence rules in that in that reference is made to an amino acid sequence without the use of a sequence identifier.

Amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids, and sequences with fewer than four specifically defined amino acids are specifically excluded from this section. The formula $X_1CX_2CX_3CX_4CX_5CX_6CX_7$, is an unbranched sequence of four or more amino acids and has more than four specifically defined amino acids. See 37 CFR 1.821 (d), "Where the description

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or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application." Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 13, 15 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed September 22, 2004.

Applicant's arguments filed January 24, 2005 have been fully considered but they are not persuasive.

Applicants maintain that the specification describes the polypeptides used in the claim method demonstrating possession of the claimed invention, and that the specification does describe a representative number of species of insecticidal proteins that meet the structural limitations of the claims. Applicants maintain that the Examiner is narrowly focused on three specific proteins described, for example, in Figure 7, i.e., TP protein, PA1b pea albumin and leginsulin, that the specification is not so limited in its description, and that Applicants have described a polypeptide having a specific formula, with a limited set of substitutions within

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certain defined locations. Applicants point out that each of the polypeptides resulting from those substitutions of X (1-7) in formula (1) is one representative specie, and that continuing with further substitutions at the X positions in formula (1) yields a second specie and so on until all of the species are envisioned. Applicants maintain that it is implausible to argue that one could not appreciate all of the species described in the specification and encompassed by the polypeptide in the claimed method, and that the Examiner's focus on three specific amino acids rather than the polypeptide formula itself is therefore improper. Furthermore, Applicants point out that they have presented an alignment in Figure 7, which as described on page, 3 lines 11-27 demonstrating 6 conserved cysteine residues, which are required in the polypeptide of formula (1) as claimed. (reply pages 6-7)

The Examiner maintains that the specification does not describe a representative number of species of insecticidal proteins that meet the structural limitations of the claims, as the specification does not describe a representative number of polypeptides resulting from the claimed formula. The Examiner also maintains that the outstanding rejection was not predicated on whether one could appreciate all of the species recited in the specification and encompassed by the polypeptide in the claimed method; the outstanding rejection was predicated on whether a representative number of species falling within the scope of the claimed genus was described. The Examiner additionally maintains that one could not appreciate all of the species recited in the specification and encompassed by the polypeptide in the claimed method, because the claimed formula defines the structure of the polypeptides, but not activity of the polypeptides. The Examiner further maintains that the focus on the three specific amino acids described in the

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specification is not improper, as the polypeptide formula claimed appears to be based on these three specific amino acid sequences.

With respect to the alignment in Figure 7, which as described on page, 3 lines 11-27 demonstrating 6 conserved cysteine residues, which are required in the polypeptide of the formula as claimed, the Examiner maintains that the alignment is also based on the three specific amino acids described in the specification, which three polypeptides are not representative of the genus of polypeptides claimed, i.e. insecticidal proteins obtained from the seeds of a legume defined by a sequence of the formula $X_1CX_2CX_3CX_4CX_5CX_6CX_7$, wherein C represents a cysteine, and wherein X_1 - X_7 represent any undefined amino acid of defined fixed intervals, or wherein X_1 - X_7 represent defined amino acids of defined intervals wherein the sequence has at least 60% identity with SEQ ID NO:6 or 7.

Claims 13, 15, 18-20 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a plant from insects comprising treating the plant with a composition comprising a polypeptide having a sequence of the disclosed TP polypeptide, does not reasonably provide enablement for methods comprising treating the plant with other compositions comprising other polypeptides having other sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed September 22, 2004.

Applicant's arguments filed January 24, 2005 have been fully considered but they are not persuasive.

Applicants maintain that this rejection is believed to be overcome at least in part, based on the definition of the polypeptide as obtained from the seeds of a legume. In addition, Applicants point out that they have described numerous species. With respect to the specific amino acid structural elements that would be retained by insecticidally active forms of these variants that would further function to protect plants from insects, Applicants maintain that guidance in this respect is provided at page 3 of the application and in the definition of the polypeptide claimed, the polypeptides used in the claimed methods all have at least the seven (7) conserved cysteine amino acids. (reply pages 7-8)

With respect to the disclosure of insecticidal polypeptides, the Examiner maintains that the specification only discloses the complete structure of a single insecticidal polypeptide (TP) purified from a single species of legume which protein comprises six cysteine residues at conserved positions, and the partial structure of an unspecified number of insecticidal polypeptides in the F1 purification fraction that are identical to TP in their first ten N-terminal amino acids and that have masses similar to that of TP.

With respect to the disclosure at page 3, the specification at page 3 discloses that insecticidal toxicity is associated with isoforms of a protein purified by the inventors from peas, which protein has a sequence similar to that of the PA1b pea albumin and which shows strong similarity (65% identity) with soybean leginsulin. The specification at page 3 also discloses that the alignment of the sequence of one of the isoforms of the protein purified by the inventors with those of the pea PA1b protein, and of soybean leginsulin is represented in Figure 7, and these 3 sequences include in particular 6 cysteine residues which occupy conserved positions. The examiner maintains that the fact that the TP protein is similar in structure to the amino acid

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sequences of two proteins that are not established as having insecticidal activity does not provide guidance with respect to which of the polypeptide sequence variants recited in the claims would have insecticidal activity and which would not, which guidance is necessary in light of the unpredictability of the sequence variants retaining the functional characteristics of the TP protein.

With respect to Applicants' assertion that at least the seven (7) conserved cysteine amino acids constitute the specific amino acid structural elements that would be retained by insecticidally active forms of these variants that would further function to protect plants from insects, the Examiner maintains that the specification does not establish that the seven (7) conserved cysteine amino acids are required for or contribute in any way to insecticidal activity.

Applicants also maintain that the Examiner appears to be confusing the burden of "undue experimentation" with the "amount of work". In this regard Applicants point to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which states: "Time and difficulty of experiments are not determinative if they are merely routine" and "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Applicants also point to page 5 of the specification as describing obtaining polypeptides from the seeds of legumes, and to Example 2 as describing how to isolate such polypeptides, and to Example 1 as describing how to confirm their insecticidal activity. Applicants additionally point out that insecticidal polypeptides within the scope of the genus claimed were obtained and described in the attached publication of Louis

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et al. Plant Science 167(2004):705-714)-see Figure 4 on page 710 and the Abstract on page 705.

(reply page 8)

The Examiner maintains that the outstanding rejection was not predicated on the amount of work required to practice the claimed invention. The outstanding rejection was predicated on the unpredictability of the sequence variants retaining the functional characteristics of the TP protein, and on the failure of the specification to provide sufficient guidance with respect to which of the polypeptide sequence variants recited in the claims would have insecticidal activity and which would not (pages 8-9 of the prior office action).

With respect to the disclosure at page 5, the Examiner maintains that page 5 does not describe how to obtain the polypeptides recited in the claims from the seeds of legumes. The disclosure at page 5 does suggest that any protein of the PA1b albumin family can be purified from seeds of legumes, but the disclosure at page 5 does not specifically disclose those proteins or their purification. With respect to Example 2, the Examiner maintains that Example 2 describes how to isolate the TP protein from peas. With respect to Example 1, the Examiner maintains that Example 1 describes how to confirm the insecticidal activity of pea meal. the Examiner maintains that these aspects of the disclosure do not provide guidance with respect to which of the polypeptide sequence variants recited in the claims would have insecticidal activity and which would not.

With respect to the disclosure of Louis S. et al. (Molecular and biological screening for insect-toxic seed albumins from four legume species. Plant Science, 2004, Vol. 167, pages 705-714), the disclosure of Louis S. et al. does not support the enablement of the claimed invention because Louis S. et al. did not obtain their results by following the disclosed methods.

Claim 13, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the office action mailed September 22, 2004.

Applicant's arguments filed January 24, 2005 have been fully considered but they are not persuasive.

Applicants argue that the rejection of Claim 13, and claims dependent thereon, under 35 U.S.C. 112, second paragraph is obviated by the amendment submitted herein (reply page 9).

The amendment submitted herein does not obviate the rejection because the amendment submitted herein does not remove all of the parentheses from the claim. It is unclear whether the subject matter enclosed within the parentheses, i.e. SEQ ID NO:1, is intended to be a claim limitation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
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CC

Cynthia Collins 4/19/05